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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,112	03/23/2006	Wolfgang Haigis	3795.05US01	8743

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EXAMINER	
SHIPMON, TIFFANY P	

ART UNIT	PAPER NUMBER
4138	

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04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,112	HAIGIS, WOLFGANG	
	Examiner	Art Unit	
	TIFFANY SHIPMON	4138	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/23/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: in paragraph [0027] the anterior surface and the retina are both referenced as being number 6 in Figure 1.

2. Also, the formulas that are found in the background of the invention section of the specification need to be included in the current US application. It cannot be referred to in another (foreign) document because it is pertinent to the specification.

Appropriate correction is required.

Drawings

3. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d).

4. Drawings appear to be missing in the filed application.

Claim Objections

5. Claims 17, 19, and 20 respectively are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 10, 12, and 16 respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object

to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Should any of claims 10, 12, or 16 be allowed, the duplicate claims will be rejected.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim(s) 6-20 are rejected under 35 USC 101 as being directed to non-statutory subject matter because these are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to another statutory class (such as a particular machine). *See* *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). See also In re Bilski (Fed Cir, 2007-1130, 10/30/2008) where the Fed. Cir. held that method claims must pass the "machine-or-transformation test" in order to be eligible for patent protection under 35 USC 101. The claimed subject matter does not require a machine to manufacture or calculate the intraocular lens (IOL) nor does it produce a physical transformation.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 6-20 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The formula used for calculation of IOL critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The claims do not include how the values needed for the IOL formula will be measured in a clear and precise manner.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 6-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. In claims 6 and 13, the phrase "to calculate intraocular lens" needs to be clarified to what is meant because intraocular lens calculations can encompass many variables. More specification is needed.

12. Claims 9 and 16 recites the limitation “the measuring instrument”. There is insufficient antecedent basis for this limitation in the claim.

13. In claims 11 and 18, the meaning if the phrase “comprises measuring to determine measured values and applying a correction value to the measured values” is unclear.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15. Claims 6 as understood is rejected under 35 U.S.C. 102(a) as being anticipated by Rosa ("A New Method of Calculating Intraocular Lens Power After Photorefractive Keratectomy"). Referring to claim 6, Rosa discloses a method for determining an optimally adapted IOL by determining pre and post refractive corneal refractive powers respectively required by the selected IOL formula before and after the surgery and utilizing those values to calculate the IOL, on page 721, column 1 paragraph 4.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 7-20 are as understood rejected under 35 U.S.C. 103(a) as being unpatentable over Rosa. Referring to claims 7 and 8, Rosa discloses calculating the corneal radius and then calculating a ratio between the calculated and measured postoperative radius is disclosed on page 721 column 2, lines 2-7. Rosa does not disclose measuring a first anterior and first posterior corneal radius before the refractive intervention; where determining the corneal refractive powers before intervention comprises deriving a first anterior corneal radius from a first posterior corneal radius from a second anterior and second posterior radius measured after the refractive intervention. If the postoperative radius was measured after the refractive intervention, it

would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Rosa, to derive and obtain a first anterior and first posterior corneal radius when the post operative data is present in order to correlate the axial length for calculating the IOL power after surgery.

18. Referring to claim 9, Rosa discloses taking into account the parameters of the measuring instrument used for measuring the second anterior and second posterior corneal radius measured after the refractive intervention as shown in Table 1 on page 722 of Rosa.

19. Referring to claim 10, Rosa discloses that the parameters of the measuring instrument taken into account comprise a keratometer refractive index on page 721, column 2, lines 2-4.

20. Referring to claim 11, Rosa discloses measuring to determine measured values and applying a correction value to the measured values on page 721 column 2 lines 13-14 and page 722 lines 1-6.

21. Referring to claim 12, Rosa discloses that the IOL power found before surgery yields the same results as using the mean post-operative corneal radii measurements on page 720 column 1 lines 9-15. Rosa does not disclose deriving the post refractive corneal radii from the preoperative corneal radii, however it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the pre refractive corneal radii from the IOL powers obtained before the intervention, to determine the post refractive corneal radii.

22. Referring to the remaining claims 13-20, Rosa discloses that to test their results, it was compared to results from the Clinical History Method and the True Corneal Power, which involve several different formulas to get the IOL on page 722, column 1 lines 1-11. Rosa does not disclose selecting the IOL formula before determining the pre and post corneal refractive powers. However, since there were different IOL formulas used in the Clinical History Method and the "true corneal power", it would have been obvious to a person of ordinary skill in the art, to combine what is disclosed in Rosa and be able to select the IOL formula before any calculations or measurements in order to decide which parameters need to be included in the for calculations in chosen formula.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Application Numbers: 7,476,248; 5,092,880; and 6,634,751 disclose how to measure eye properties before and after surgeries.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY SHIPMON whose telephone number is (571)270-1448. The examiner can normally be reached on Monday thru Friday, 8AM-5 PM, Est., alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bumgarner Melba can be reached on 571-272-4709. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melba Bumgarner/
Supervisory Patent Examiner, Art Unit 4138

/TIFFANY SHIPMON/
Examiner, Art Unit 4138